K082957

510 (k) Summary

As Required by 21 section 807.92 (c)

MAY 29 2009

1. **Submitter Name:** Siam Sempermed Corp., Ltd
2. **Address:** 352 Kanjanavanit Road. Pahtong Hatyai Songkhla.Thailand 90230
3. **Phone:** (+66) 74 291 471
4. **Fax:** (+66) 74 471 337
5. **Contract Person:** Mrs. Parawan Paiyasan(Quality System Manager)
6. **Date summary prepared:** September 22, 2008
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 13900 49th Street North Clearwater, USA , FL 33762
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E. Harris

12. **Device Trade or Proprietary Name:** Non sterile, Powder free Nitrile Examination Glove, Blue with Polymer coating, Tested for use with chemotherapy drugs.

13. **Device Common or usual name:** Examination glove

14. **Device Classification Name:** Nitrile Patient Examination Glove (Powder Free(Polymer coated),Blue color)

15. **Description of the Device:**
Non sterile, Powder free Nitrile Examination Glove, Blue with Polymer coated, Tested for use with chemotherapy drugs.

16. **Indications for se of the device:** Based upon 21 CFR Prt 880.6250: "Patient examination glove." A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

17. **Summary of The Technological Characteristics of The devices:**
Non sterile, Powder free Nitrile Examination Glove, Blue with Polymer coated, Tested for use with chemotherapy drugs are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 6319-00a-05	Meets
Physical Properties	ASTM D 6319-00a-05	Meets
Freedom from pinholes	ASTM D 6319-00a-05	Meets
Powder Free Residue	ASTM D 6124-06	Meets
Biocompatibility	Primary Skin Irritation in Rabbits	Passes
	Guinea Pig Sensitization	Passes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siam Sempermed Corporation
C/O Mr. William E. Harris
President & CEO
Sempermed USA, Incorporated
13900 49th Street North
Clearwater, Florida 33762

MAY 29 2009

Re: K082957
Trade/Device Name: Non-Sterile, Powder-Free Nitrile Examination Glove, Blue with Polymer Coating, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: May21, 2009
Received: May 26, 2009

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Siam Sempermed Corp. Ltd.

510(k) Number: K082957

Device Name: Non-Sterile, Powder-Free Nitrile Examination Glove, Blue with Polymer Coating, Tested for Use with Chemotherapy Drugs

Indications for Use: Based upon 21 CFR Part 880.6250; "Patient examination glove"

A patient examination glove is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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